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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/362,485	07/28/99	FLOHE	L 29473/35834

HM22/0427  
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EXAMINER

JOHANNSEN, D

ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

*9*  
04/27/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/362,485**

Applicant(s)  
**Flohe et al**

Examiner  
**Diana Johannsen**

Group Art Unit  
**1655**



☒ Responsive to communication(s) filed on Oct 29, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-18 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to kits comprising L-alanine, NAD, PMS, and NBT, classified in class 435, subclass 810, class 536, subclass 26.24, and class 562, subclass 553.
  - II. Claims 2-8, 14-15, and 17-18, drawn to methods of diagnosing mycobacterial infections comprising measuring alanine dehydrogenase activity, classified in class 435, subclass 26.
  - III. Claims 9-13 and 16, drawn to nucleic acids and methods for detecting mycobacterial infections by detection of nucleic acids, classified in class 435, subclasses 6 and 91.2, and class 536, subclasses 23.7, 24.32, and 24.33.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed products may be employed in materially different processes. For example, L-alanine may be employed in *in vitro* protein synthesis, while NAD,

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PMS, and NBT may be employed in, e.g., methods for measuring activity of a protein such as inosine 5'-monophosphate dehydrogenase.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. The reagents of Invention I are disclosed as capable of use in methods of measuring alanine dehydrogenase activity, but not in the methods of detecting and differentiating nucleic acids of Invention III. Further, the reagents of Invention I (L-alanine, NAD, PMS, and NBT) have different structures and functions than the nucleic acids of Invention III. For example, while the reagents of Invention I function in methods of protein synthesis and/or methods of measuring enzymatic activity, the nucleic acids of Invention III function in methods of, e.g., nucleic acid hybridization or amplification.

Inventions II and III are drawn to patentably distinct methods. While each of the Inventions is directed to methods that may result in diagnosis of mycobacterial infections, the methods require one to perform unrelated, patentably distinct process steps. For example, the methods of Invention II require steps of measuring adsorption to achieve the objective of measuring alanine dehydrogenase activity, while the methods of Invention III require steps of nucleic acid hybridization to achieve the objective of detecting particular nucleic acids of interest. Accordingly, the two inventions are distinct from one another.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because inventions I-III require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. A telephone call was made to James P. Zeller on April 12, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday from 7:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at 703/308-1152. The fax phone number for the

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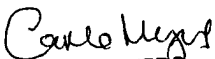
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Technology Center where this application or proceeding is assigned is 703/305-3014 or 305-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana Johannsen

April 24, 2000

  
CARLA J. MYERS  
PRIMARY EXAMINER